

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA
AT CLARKSBURG**

NOVARTIS PHARMACEUTICALS
CORPORATION, NOVARTIS
CORPORATION, NOVARTIS AG, and
NOVARTIS PHARMA AG,

Plaintiffs,

v.

MYLAN INC. and MYLAN
PHARMACEUTICALS, INC.,

Defendants.

Civil Action No. 1:14-cv-111-IMK

**PLAINTIFFS' REPLY MEMORANDUM IN SUPPORT OF MOTION TO STAY
LITIGATION PENDING RESOLUTION OF JURISDICTIONAL CHALLENGE TO
FIRST-FILED DELAWARE CASE**

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TABLE OF CONTENTS

I. INTRODUCTION1

II. ARGUMENT.....1

 A. The Issue of Whether Delaware Has Personal Jurisdiction Over Mylan Is Not
Before This Court1

 B. The First-to-File Rule Applies Here3

 C. Mylan Has Not Shown That A Departure From the First-to-File Rule Is
Warranted.....5

 D. Mylan Has Not Identified Any Compelling Reasons That Weigh Against Staying
This Second-Filed Case5

III. CONCLUSION.....6

TABLE OF AUTHORITIES

	Page(s)
FEDERAL CASES	
<i>AstraZeneca AB v. Mylan Pharm., Inc.</i> , C.A. No. 14-696-GM (D. Del. 2014), ECF No. 26 (Opening Br. Ex. A).....	2, 3
<i>Elderberry of Weber City, LLC v. Living Centers-Southeast, Inc.</i> 2013 WL 1164835 (W.D. Va. Mar. 20, 2013).....	4
<i>Electronics for Imaging, Inc. v. Coyle</i> , 394 F.3d 1341 (Fed. Cir. 2005).....	1, 2
<i>Genentech, Inc. v. Eli Lilly & Co.</i> , 998 F.2d 931 (Fed. Cir. 1993).....	1, 5
<i>Harris v. McDonnell</i> , No. 5:13-cv-00077, 2013 WL 5720355 (W.D. Va. Oct. 18, 2013)	4
<i>Pfizer Inc. v. Apotex Inc.</i> , 640 F. Supp. 2d 1006 (N.D. Ill. 2009)	2
<i>Pfizer, Inc. v. Mylan, Inc.</i> , No. 1:09-cv-79, slip op. (N.D. W. Va. Nov. 20, 2009) (Keeley, J.).....	2, 3, 5
<i>Quesenberry v. Volvo Grp. N. Am, Inc.</i> 2009 WL 648658 (W.D. Va. Mar. 10, 2009).....	4
<i>Schering Corp. v. Caraco Pharm. Labs., Ltd.</i> , No. 06-cv-14386, 2007 WL 1648908 (E.D. Mich. June 6, 2007)	2
<i>West Virginia Highlands Conservancy v. Monongahela Power Co.</i> , No. 1:11cv71, 2012 WL 11122 (N.D. W. Va. Jan. 3, 2012) (Keeley, J.) (Opp. 6)	6
<i>Z-Man Fishing Prods., Inc., v. Applied Elastomerics, Inc.</i> , No. 2:06-2022-CWH, 2006 WL 3813707 (D.S.C. Dec. 27, 2006)	1, 5
FEDERAL STATUTES	
21 U.S.C. § 355(j)(5)(B)(iii)	5
35 U.S.C. § 271(e)(2).....	3

I. INTRODUCTION

Mylan does not dispute the heavy presumption favoring the forum of the first-filed suit. *See Genentech, Inc. v. Eli Lilly & Co.*, 998 F.2d 931, 938 (Fed. Cir. 1993). Nor does Mylan dispute that it bears the burden of establishing a basis to depart from the first-to-file rule. *See Z-Man Fishing Prods., Inc. v. Applied Elastomerics, Inc.*, No. 2:06-2022-CWH, 2006 WL 3813707, at *4 (D.S.C. Dec. 27, 2006) (the party seeking to have the second-filed action take priority has the burden to show why the first-to-file rule should not apply). Nor has Mylan identified any compelling reason for this Court to deny Novartis's request for a brief stay of this action pending the District of Delaware's determination as to whether it has personal jurisdiction over Mylan in Novartis's first-filed action. Instead, Mylan spends the bulk of its opposition arguing the merits of its pending motion to dismiss in Delaware. *See, e.g.*, Opp. 3-6. That issue is more properly left to the Delaware court to resolve, in a decision likely to issue in a matter of two to three months. Accordingly, this Court should grant Novartis's Motion to Stay to permit the Delaware court to decide the issue.

II. ARGUMENT

A. The Issue of Whether Delaware Has Personal Jurisdiction Over Mylan Is Not Before This Court

Mylan argues that the Court should depart from the first-to-file rule and deny Novartis's motion because Delaware lacks personal jurisdiction over Mylan. Opp. 4-6. In support, Mylan cites *Electronics for Imaging, Inc. v. Coyle*, 394 F.3d 1341 (Fed. Cir. 2005), which lists, as one of many factors that a court can consider in determining whether to depart from the first-to-file rule, the "absence of jurisdiction over all necessary or desirable parties." Opp. 4. However, Mylan has failed to prove that there is such an absence. Nor could it, because the Delaware court has not yet ruled whether it has jurisdiction over Mylan. Rather than wait for the Delaware court

to decide that dispute, Mylan asks this Court to apply Delaware state and federal case law, and reach its own decision. Opp. 5-6. Such an approach would conflict with the weight of authority and result in the sort of waste of judicial and party resources that Novartis seeks to prevent with this motion. *See, e.g.*, Opening Br. Ex. F, *Pfizer, Inc. v. Mylan, Inc.*, No. 1:09-cv-79, slip op. at 8 n.4 (N.D. W. Va. Nov. 20, 2009) (Keeley, J.) (granting motion to transfer “protective suit” brought under the Hatch-Waxman Act, in part, because “the first-filed court must determine whether an exception to the first-to-file rule applies”); *Pfizer Inc. v. Apotex Inc.*, 640 F. Supp. 2d 1006, 1010-11 (N.D. Ill. 2009) (staying a protective suit pending the resolution of a jurisdictional dispute in the first-filed case); *Schering Corp. v. Caraco Pharm. Labs., Ltd.*, No. 06-cv-14386, 2007 WL 1648908, at *3 (E.D. Mich. June 6, 2007) (same).¹

Even if it were proper to debate the merits of Mylan’s motion to dismiss here—and it is not—Judge Sleet recently found that Mylan *is* subject to personal jurisdiction in Delaware based on facts almost identical to those in this case. *See* Opening Br. at 1-2 (citing *AstraZeneca AB v. Mylan Pharm., Inc.*, C.A. No. 14-696-GMS (D. Del. 2014), ECF No. 26 (Opening Br. Ex. A)). Specifically, Judge Sleet found specific jurisdiction because Mylan’s activities (*e.g.*, filing an ANDA and sending notice of a paragraph IV certification) were purposefully directed to the “state of Delaware, where [the plaintiff] is organized” and because the “consequences” of those actions were (and will be) “suffered in Delaware.” Opening Br. Ex. A, *AstraZeneca AB*, C.A. No. 14-696-GMS at 14. In this case, Mylan likewise filed an ANDA and served a paragraph IV

¹ Mylan’s attempt to distinguish these cases on the basis that only a subset of the defendants were challenging jurisdiction (Opp. 11) is unavailing. When deciding whether to depart from the first-to-file rule, a court may consider whether there is an “absence of jurisdiction over *all necessary or desirable* parties.” *See Electronics for Imaging*, 394 F.3d at 1348 (emphasis added). As a consequence, the analysis under this factor is the same whether all defendants challenge jurisdiction or only a subset do. In either case, the first-filed court should decide whether a departure from the first-to-file rule is proper.

notification on a Delaware corporation—Novartis Pharmaceuticals Corporation. In so doing, it purposefully directed its activities to the state of Delaware, and the consequences of Mylan’s actions are (and will be) suffered in Delaware. Therefore, the *AstraZeneca* case indicates Mylan would be subject to specific personal jurisdiction in Delaware.²

B. The First-to-File Rule Applies Here

As Mylan acknowledges, courts consider three factors in determining whether to apply the first-to-file rule: (1) the chronology of the filings; (2) the similarity of the parties involved; and (3) the similarity of the issues between the two actions. *See* Opp. 10 (citing *Harris v. McDonnell*, No. 5:13-cv-00077, 2013 WL 5720355, at *3 (W.D. Va. Oct. 18, 2013)). Mylan does not dispute that the second and third factors weigh in favor of a stay, and for good reason—the parties and claims in the present action are identical to those in the case pending in Delaware. Moreover, Mylan’s assertion that the chronology factor weighs against application of the first-to-file rule is incorrect for at least the following three reasons.

First, there is no dispute that the Delaware action was first-filed. *See* Opening Br. Ex. C, D. Del. Compl. filed on June 25, 2014; N.D. W. Va. Compl. filed on June 26, 2014 (D.I. 1).

Second, the proximity of the filing dates is immaterial; a mere difference of hours has been held to trigger the first-to-file rule. In a factually similar Hatch-Waxman case, this Court held that the chronology factor was satisfied when the difference in filing time was less than five hours. *See* Opening Br. Ex. F, *Pfizer, Inc. v. Mylan, Inc.*, No. 1:19-cv-79, slip op. (N.D. W. Va.

² Although Mylan did not send its EXJADE® paragraph IV certification to a Delaware street address, it did send that certification to Delaware-incorporated Novartis Pharmaceuticals Corporation. Therefore, Novartis’s cause of action—the “artificial” injury created by 35 U.S.C. § 271(e)(2)—arose out of Mylan’s contact with a Delaware citizen, and “Mylan cannot plausibly argue that it could not ‘reasonably anticipate being haled into court’ in Delaware.” *See* Opening Br. Ex. A, *AstraZeneca AB*, C.A. No. 14-696-GM at 15.

Nov. 20, 2009) (Keeley, J.), at 1-2, 7 (concluding that “the ‘chronology’ prong weighs in favor of the [first-filed jurisdiction]” where first complaint was filed at 11:28 A.M. and second complaint was filed at 4:01 P.M. on the same day).

The cases cited by Mylan to evade the rule are inapposite. In *Harris v. McDonnell* (Opp. 10), the issue was not only timing, but that the complaint in the first-filed case had been amended to include additional claims *after* the second complaint was filed. 2013 WL 5720355, at *4. In contrast (and as Mylan appears to concede) the complaints pending in Delaware and this Court are virtually identical. And in both *Quesenberry v. Volvo Grp. N. Am, Inc.* 2009 WL 648658 (W.D. Va. Mar. 10, 2009) and *Elderberry of Weber City, LLC v. Living Centers-Southeast, Inc.* 2013 WL 1164835 (W.D. Va. Mar. 20, 2013), the second-filed court refused to grant a stay when the first-filed case was a declaratory judgment action. Refusal to apply the first-to-file rule in those two cases served to protect the *plaintiff’s* right to choose its litigation forum. Here, Novartis, *i.e.*, the plaintiff, chose the District of Delaware, so entry of a stay in this action would be in accord with *Quesenberry* and *Elderberry*.

Third, contrary to Mylan’s assertions (Opp. 10), there is no meaningful difference in the progress of the Delaware and West Virginia actions. Absent Mylan’s motion to dismiss, its answer in Delaware would have been due five months ago. Accordingly, the fact that Mylan has filed an answer in this Court hardly counsels against a stay; it will have 14 days to file an answer in the Delaware case if its pending motion to dismiss is denied. Mylan also overstates the delay likely to result from awaiting a decision on the motion to dismiss. Mylan’s own research shows that Judge Andrews averages 6.4 months from motion filing to decision. Opp. 7 at n.8; Opp. Ex. C at 5 (2014). By that calculation, a decision on jurisdiction is likely to issue in the next two to three months.

C. Mylan Has Not Shown That A Departure From the First-to-File Rule Is Warranted

Departure from the first-to-file rule requires a “sound reason that would make it unjust or inefficient to continue the first-filed action.” *Genentech*, 998 F.2d at 938. The court presiding over the first-filed action—not the second-filed action—should evaluate whether exceptions to the first-to-file rule apply. *See* Opening Br. Ex. F, *Pfizer, Inc.*, at 8 n.4. Mylan has failed to meet its burden to show an exception applies. *See Z-Man Fishing Prods., Inc.* No. 2:06-2022-CWH, 2006 WL 3813707, at *4. However, even if this Court were to take up the issue of departing from the first-to-file rule (which it should not), Mylan does not—and cannot—argue that Novartis has engaged in either forum shopping or bad faith by filing suit in West Virginia. Accordingly, this Court should grant Novartis’s Motion.

D. Mylan Has Not Identified Any Compelling Reasons That Weigh Against Staying This Second-Filed Case

Mylan will not be harmed by a short stay pending the Delaware court’s decision on the motion to dismiss. A decision on Mylan’s motion to dismiss is likely imminent, and should come down in a couple of months. Further, contrary to Mylan’s suggestion, Novartis is not asking for a stay pending final resolution of the jurisdictional issue (for example, a decision by the Supreme Court). Rather, Novartis requests a short stay pending a decision from the Delaware District Court.

This short delay will neither unduly prejudice Mylan nor significantly delay the potential launch of Mylan’s generic drug. Regulatory approval of Mylan’s drug has already been stayed for thirty months pursuant to 21 U.S.C. § 355(j)(5)(B)(iii), and a delay of two to three months until a ruling on the pending motion to dismiss will permit the case to be resolved before the end of the stay period. Mylan will not be unreasonably harmed by a short stay. Nor will the public be wrongfully deprived of access to Mylan’s generic product.

Mylan's reliance on *West Virginia Highlands Conservancy v. Monongahela Power Co.*, No. 1:11cv71, 2012 WL 11122 (N.D. W. Va. Jan. 3, 2012) (Keeley, J.) (Opp. 6) is misplaced. In *Monongahela*, this Court refused to stay a citizen suit under the Clean Water Act. 2012 WL 11122 at *5. In support of a stay, the defendant power company offered an email exchange between itself and the West Virginia Department of Environmental Protection requesting the reclassification of the designated use of a stream. *Id.* at *2. Reclassification required the amendment of the West Virginia Code of State Rules through a formal state rulemaking process, a process which this Court found to be "steeped in uncertainty". *Id.* at *5. By contrast, the Delaware motion to dismiss has been fully briefed and is awaiting a decision.

If Mylan wishes to start discovery pending a decision on its motion to dismiss, Novartis is willing to do so on the understanding that *first*, such discovery is not deemed to have taken place in either the first-filed Delaware case or this second-filed case, and *second*, if the Delaware court determines that it has personal jurisdiction over Mylan, said discovery shall apply in the first-filed Delaware case, and if the Delaware court determines that it does not have personal jurisdiction over Mylan, said discovery shall apply in this second-filed case.

III. CONCLUSION

For the reasons set forth above, and in its opening brief, Novartis respectfully requests that this Court stay this second-filed case pending the resolution of Mylan's Motion to Dismiss the First-filed Delaware Complaint for Lack of Personal Jurisdiction.

Dated: December 15, 2014

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CERTIFICATE OF SERVICE

I hereby certify that on December 15, 2014, the foregoing PLAINTIFFS' REPLY MEMORANDUM IN SUPPORT OF MOTION TO STAY LITIGATION PENDING RESOLUTION OF JURISDICTIONAL CHALLENGE TO FIRST-FILED DELAWARE CASE was electronically filed with the Clerk of the Court using the CM/ECF system, which will send notification to the following registered attorneys of record that the document has been filed and is available for viewing and downloading:

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